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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/666,644

09/18/2003

Giuseppe Lombardo

ZL 0189

8511

23367

7590

08/25/2006

GENE WARZECHA  
LINVATEC CORPORATION  
11311 CONCEPT BOULEVARD  
LARGO, FL 33773

EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3733

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/666,644	<b>Applicant(s)</b> LOMBARDO ET AL.	
	<b>Examiner</b> James L. Swiger	<b>Art Unit</b> 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-2, and 5-13 is/are rejected.
- 7) ☒ Claim(s) 3 and 4 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments filed 6/5/2006 have been fully considered but they are not persuasive. With regards to, in general, applicant's arguments concerning *the second predetermined distance being less than the first predetermined distance*, the examiner agrees with the fault in the reference of Torrie, however, this limitation is still readable on the disclosed art. See rejection below.

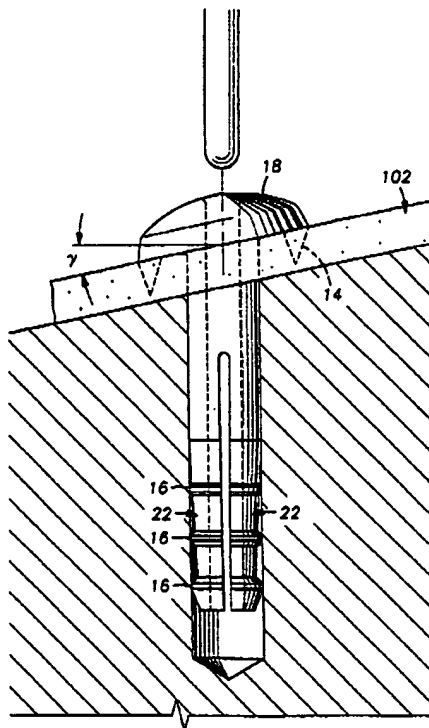
With regards to the arguments in regards, to the outwardly extending protrusions or barbs, Dudasik is still considered to have barbs as disclosed before for engaging bone and/or tissue, and also the reference of Zang et al. shows that the protrusions may also be made into individual rows (see Fig. 3) or treated as much for that kind of fixation.

The following rejections still apply:

### ***Claim Rejections - 35 USC § 103***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2, 6-9, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Torrie et al. (U.S. Patent No. 5,601,558) in view of Hunt (US Patent 324,768). Torrie et al. disclose an invention of a soft tissue anchor having an elongated shaft (see Fig. 6 below), a bone engaging means (16), and a transverse head (see Figure 6 below) with a first and second points positioned a certain distance outward from the axis and a first and second projection positioned distally from the first and second points.



Torrie et al. also disclose a lumen (See Fig. 6 above) extending from the proximal (head of anchor) to the distal end, respective ramps going to the first and second projections (See Fig. 6 above), and a bone engaging means that is considered the outwardly extending barbs of the distal end of the anchor shown above (items 16 and 22, and also see Col. 4, lines 1-10). Torrie et al. disclose the claimed invention except for a transverse head that has a second predetermined distance being less than the first predetermined distance. Hunt discloses a head having a second predetermined distance less than a first (a), see fig. 5. This modification allows the screw to be better secured once it is placed (see page 1, lines 1-30). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the screw of Torrie et al. having at least an offset first and second predetermined distances in view of Hunt to better secure the screw.

With regards to claims 12 and 13 it should be noted that in addition to the bone engaging means noted in the paragraph immediately supra (the outward barbs), the distal projections may also be considered the tissue-engaging means capable of holding labral tissue adjacent to the glenoid fossa (See col. 3, lines 36-44).

Claims 5 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torrie et al. '558 in view of Dudasik (U.S. Patent No. 6,648,893). Torrie et al. discloses the claimed invention except for a device having a transverse bottom surface that is arcuate between the first and second points, and also an arcuate distance subtended by a barb in a row being greater than that subtended by the immediately distally adjacent barb in that row. Dudasik teaches a transverse bottom surface that is arcuate between points (see area adjacent to 129 in Fig. 8) that allows for better engagement of the tissue and bone (Col. 5, lines 1-5) and an arcuate distance in its barbs, smaller in the distal direction, for a better fit to the bone (Col. 5, lines 11-28). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Torrie et al. having at least a transverse, arcuate bottom between the first and second points, and barbs subtended with respect to the ones distal in view of Dudasik to better secure the anchor to the bone.

With further regards to claim 10, Torrie et al. discloses the claimed invention except for an arcuate area that gets smaller towards the distal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the direction subtended barbs of Torrie et al. in view of Dudasik, since it has

been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167.

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zang et al. (U.S. Patent No. 5,720,766). Zang et al. discloses a soft tissue anchor having a shaft (44) with radially outwardly extending projections capable of being barbs (46) extending in longitudinal rows that are also capable of being a tissue engaging means towards the proximal end of the shaft (See Fig. 3).

Zang et al. does not disclose, however, barbs that have a smaller width in the direction of the distal end, for better securing the anchor into the bone. Dudasik discloses a device having barbs that vary in width allowing better attachment to the bone for more secure attachment of the anchor (Col. 5, lines 11-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Zang et al. having at least barbs with a longitudinally-varying width in view of Dudasik to better secure the anchor to the bone in use.

With further regards to claim 11, Zang et al. discloses the claimed invention except for a width area that gets smaller towards the distal end. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reverse the direction subtended barbs of Zang et al. in view of Dudasik, since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. In re Einstein, 8 USPQ 167

***Allowable Subject Matter***

Claims 3 and 4 are objected to as being dependent upon a rejected base claim,

but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

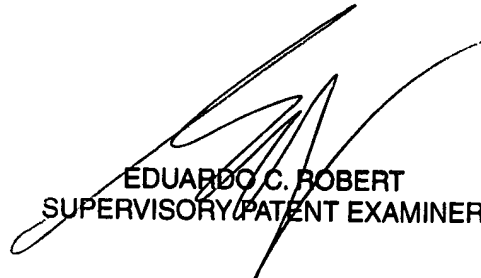
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



JLS



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SUPERVISORY PATENT EXAMINER